cells of one or more FSH or FSH Mimetic stimulated genes, comprises using a solid surface on which a group of probes is immobilized, the probes consisting of one or more of the sequences set forth in SEQ ID NOS. 1-15.

a5

15. The method of claim 7, wherein determining the level of expression in the sample of cells of one or more FSH or FSH Mimetic stimulated genes, comprises using a solid surface on which a group of probes is immobilized, the probes consisting of one or more of the sequences set forth in SEQ ID NOS. 1-15.

REMARKS

Claims 1, 3, 5 and 7 have been amended. New claims 12-15 were added. No new matter is presented by virtue of these amendments. Support for the within amendments can be found throughout the specification and in the original claims of the application. For instance support for new claims 12-15 is established at page 11, lines 13-26, in particular, lines 21-23.

As an initial matter, Applicant notes that the pending claims of the application have been amended to recite those sequence listings corresponding to certain FSH and FSH Mimetic stimulated genes which appear in both Tables 1 and/or 3 of the application. Such amendments are amply supported by the specification and original claims of the application, and are well within the scope of the prior search. Additionally, support for those amendments to claims 1, 3, 5 and 7 which relate to the two-fold increase in expression, is amply supported by the data provided in the tables of the application, wherein all the listed genes (corresponding to SEQ ID NOS 1-15) are at least two-fold upregulated. Further, support for those amendments to claims 1, 3, 5 and 7 which relate to the human genes homologous to FSH and FSH Mimetic stimulated genes appears at pages 17-19 of the application.

Referring now to the Office Action, an objection to the title is acknowledged. Applicant has amended the title in order to be clearly indicative of the invention to which the claims are directed. Withdrawal of the objection is requested.

Claims 1, 3, 5 and 7 stand rejected under 35 USC §112, second paragraph. Objection is made to reference of "Tables 1, 2 and 3" as it appears in the claims. Additionally, the terms "different", "increased" and "altered" as they appear in the noted claims are objected to as allegedly rendering the claims indefinite. The Office Action goes on to state various other informalities.

Applicant submits that the noted claims are indeed definite when read in view of the supporting specification, as is proper. However, it is respectfully submitted that the within amendments obviate the rejection. In particular, each of the objectionable phrases has been clarified or deleted. Withdrawal of the §112, second paragraph rejection, is thus requested.

Claims 1, 3, 5 and 7 stand rejected under 35 USC §112, first paragraph.

While Applicant disagrees with the rejection, in order to expedite prosecution of the application, Applicant has amended the claims to further define the present invention and to recite the certain relevant sequence identifiers. Applicant also submits herewith a sequence listing in paper and electronic format. The sequence listing includes the sequences for those FSH and FSH Mimetic stimulated genes to which the amended claims are now directed.

By way of further explanation and for clarity, attention is directed to the example set forth in the application at pages 35-37. That example discloses four groups of genes (tables 1-4), whose expression is upregulated at least two-fold in Y-1 cells after 16 hours from exposure to a specific inducer of adenylate cyclase related to gonadal functions and reproduction in humans (FSH and an FSH mimetic; table 1 and 3), to a non-specific activator of adenylate cyclase (forskolin; table 4), or to a combination of all these compounds (table 2).

A comparison of those tables enables identification of specific groups of genes which fall under one or more of these categories. Given the scope of the invention (see, e.g., the application at page 1, line 22 to page 2, line 8), genes of particular interest are those genes whose expression is specifically upregulated by FSH or by a FSH mimetic, but not by Forskolin.

A comparison of the four tables shows that 15 genes, all identified in tables 1 and/or 3 as IMAGE clone or GenBank Accession number, are specifically up-regulated by FSH, or by FSH as well as by an FSH mimetic, but not by the non-specific inducer Forskolin. These genes are summarized in the following Table 5.

Table 5

SPECIFIC INDUCER	IMAGE CLONE NO.	GENBANK ACC. NO.	LOCATION	SEQ ID NO:
FSH ALONE	474339	AA038657	Pg. 44, ln. 25	1
	420070	W90900	Pg. 44, ln. 29	2
	482029	AA059893	Pg. 45, ln. 8	3
	637891	AA189583	Pg. 44, ln. 25	4
	619501	AA175510	Pg. 45, ln. 26	5
	441229	AA011839	Pg. 45, ln. 28	6
	481400	AA060500	Pg. 45, ln. 30	7
	574608	AI323606	Pg. 45, ln. 31	8
FSH OR FSH MIMETIC	337748	W29492	Pg. 45, ln. 22 Pg. 56, ln. 1	9
	751826	AA396152	Pg. 45, ln. 13 Pg. 54, ln. 8	10
	681159	AA242573	Pg. 45, ln. 5 Pg. 56, ln. 10	11
	805842	AA399854	Pg. 45, ln. 1 Pg. 54, ln. 16	12
	441346	AA009268	Pg. 44, ln. 27 Pg. 56, ln. 9	13
	406031	W84014	Pg. 44, ln. 6 Pg.55, ln. 29	14
	444027	AA014915	Pg. 44, ln. 26 Pg. 55, ln. 18	15

As shown, Table 5 provides corresponding information for the specific inducer, IMAGE clone, GenBank No., location in the application, and relevant SEQ ID NOS. As noted above, a sequence listing in paper and electronic form is submitted herewith for SEQ. ID NOS 1-15.

Thus, claims 1, 3, 5, and 7 have been amended to recite those sequences identified in Table 5 above corresponding to SEQ ID NOS: 1-15. Applicant submits that the selected transcripts, being considerably and durably over-expressed in the conditions set forth in the claims of the application,

are highly preferred and of critical importance relative to those transcripts expressed in only one of the experimental protocols for FSH and FSH Mimetic induction which lead to the establishment of the tables 1-4.

In further support of Applicant's arguments, it is noted that Y-1 cells are a clonal steroid-secreting cell strain initiated from a mouse adrenal cortex tumor (Yasumura Y et al., *Cancer Res.* 26: 529-536, 1966, courtesy copy enclosed), which has been deposited in ATCC under the catalogue code CCL-79 (as indicated in the application at page 35, lines 22-23). Y-1 cells have been described in several articles on the study of the expression and regulation of hormones such as progesterone.

In particular, Y-1 cells, when stably expressing the human gene for FSH receptor, are well known to secrete progesterone if exposed to human FSH since human FSH receptor is functionally active when expressed in these mouse adrenal cells. Therefore, the skilled person in the art would readily understand the origin and features of the cells used in the example of the application, and how to reproduce the results commensurate in scope with the invention.

Accordingly, withdrawal of the §112, first paragraph, rejection is thus requested.

Claims 5 and 7 stand rejected under 35 USC §102(b) over Kameda et al (*Biochem. Biophys. Acta* 1445:31-38).

Claims 1, 3, 5 and 7 stand rejected under 35 USC §102(b) over Orly et al (*Endocrinology* 134:2336-46).

Each of the rejections is traversed. Neither of the cited references teaches or suggests Applicant's invention in a manner to sustain a rejection under §102.

However, while Applicant disagrees with the basis for the rejection, it also is believed to be obviated by the within amendment. In particular, claims 1, 3, 5 and 7 have been amended to recite

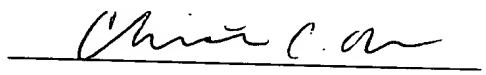
those genes identified by SEQ ID NOS 1-15.

The cited references, even if combined, do not teach or suggest the specificity of the upregulation associated with FSH when compared to a non-specific inducer such as Forskolin. Additionally, the cited references do not teach or suggest Applicant's invention, e.g., methods for agent identification or monitoring cellular processes, in any manner sufficient to sustain the §102 rejection.

In view of the foregoing, Applicant submits that present claims 1, 3, 5 and 7 are clearly allowable. Reconsideration and withdrawal of the rejections are requested.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES

(Additions are underlined; deletions are bracketed.)

IN THE SPECIFICATION:

The title of the invention was amended as follows:

[FOLLICLE STIMULATING HORMONE STIMULATED GENES AND USES THEREOF]

METHODS FOR MONITORING FSH OR FSH MIMETIC INFLUENCED CELLULAR PROCESSES

A sequence listing was inserted between page 37 (the last page of the specification) and page 38 (the first page of the claims).

IN THE CLAIMS:

Claims 1, 3, 5, and 7 were amended as follows.

1. A method for identifying an agent which modulates an FSH or FSH Mimetic influenced cellular process or response, the method comprising:

a) exposing a sample of cells to FSH or FSH Mimetic;

b) determining the level of expression in the sample of cells of one or more FSH [OR] or FSH Mimetic stimulated genes [(Tables 1, 2, 3)] selected from the group consisting of those set forth in SEQ ID NOS. 1-15 and human genes homologous to said genes, in the presence and absence of a selected agent; and

c) identifying that the agent modulates an FSH or FSH Mimetic influenced cellular process or response when the expression of the one or more FSH or FSH Mimetic stimulated genes in the cell sample in the presence of the agent differs by at least a two-fold increase over [from] the expression of the one or more FSH or FSH Mimetic stimulated genes in the absence of the agent.

3. A method for identifying an agent which modulates an FSH or FSH Mimetic

influenced cellular process or response, the method comprising:

a) providing a sample of cells;

b) determining the level of expression in the sample of cells of one or more FSH or FSH Mimetic stimulated genes [(Tables 1, 2, 3)] selected from the group consisting of those set forth in SEQ ID NOS. 1-15 and human genes homologous to said genes, in the presence and absence of a selected agent; and

c) identifying that the agent modulates an FSH or FSH Mimetic influenced cellular process or response when the expression of the one or more FSH or FSH Mimetic stimulated genes in the cell sample in the presence of the agent differs by at least a two-fold increase over [from] the expression of the one or more FSH or FSH Mimetic stimulated genes in the absence of the agent.

5. A method for detecting or monitoring a cellular process or response that is influenced by FSH or FSH Mimetic, the method comprising:

a) obtaining a sample of cells from a patient;

b) determining the level of expression in the sample of cells of one or more FSH or FSH Mimetic stimulated genes [(Tables 1, 2, 3)] selected from the group consisting of those set forth in SEQ ID NOS. 1-15 and human genes homologous to said genes; and

c) identifying that the cells in the sample of cells obtained from the patient are undergoing a cellular process or response that is influenced by FSH or FSH Mimetic when the level of expression of the one or more FSH or FSH Mimetic stimulated genes in the cell sample [is increased] exhibits at least a two-fold increase relative to the level of expression of the one or more FSH or FSH Mimetic stimulated genes in a control the sample.

7. A method for assessing whether cells will be responsive to an agent which modulates an FSH or FSH Mimetic influenced cellular process or response comprising the steps of

a) exposing a sample of cells obtained from a patient to a test agent;

b) determining the level of expression in the sample of cells of the one or more FSH or

FSH Mimetic stimulated genes [(Tables 1, 2, 3)] selected from the group consisting of those set forth in SEQ ID NOS. 1-15 and human genes homologous to said genes, in the sample exposed to the agent and in a sample of cells that is not exposed to the agent; and

c) determining that the cells will be responsive to the agent when [20] expression of the one or more of the FSH or FSH Mimetic stimulated genes [is altered] exhibits at least a two-fold increase in the presence of the agent relative to the expression of the one or more FSH or FSH Mimetic stimulated genes in the absence of the agent.

New claims 12-15 were added.